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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,513	07/03/2001	Gregory J. LaRosa	1855.1052-020	5309

7590 11/08/2002

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/898,513	LaRosa et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 11, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above, claim(s) *11-36* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10 and 37-43* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5, 6, 8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-43 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Election/Restriction

Applicant's election with traverse of Group I (claims 1-10, 37-43) in Paper No. 9 is acknowledged. However, since no argument was set forth by the applicant the election was treated as an Election **without** traverse. Hence, claims 11-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected . Claims 1-10, 37-43 are considered.

Applicants are reminded to cancel the claims to the non elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Please update the information by including the issued patent number.

Claim Rejections - 35 USC § 112

Claims 1-10, 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10, 37-43 are vague and indefinite for recitation of "antigen-binding fragment thereof", the intended "binding fragment(s)" are not defined. The metes and bounds of the intended regions are not defined. In addition, the claim is vague and unclear since they do not indicate where the antibodies are binding to, are the antibodies binding to the C-terminal region? The claims have been interpreted in light of the specification and since the specification does not set forth clear definition of the regions wherein an antibody or antibodies can recognize CCR2, the claims are considered to be vague and indefinite.

Claim Rejections - 35 USC § 112

Claims 1-10, 37-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody directed against the amino-terminal region of CC-chemokine receptor 2 (CCR2), does not reasonably provide enablement for any and all antibodies against all regions of CCR2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Applicants are reminded that this field is highly

unpredictable as applicants' own assertions in the specification is testament to the unpredictability of the field. In addition, the teaching of the specification does not provide adequate teaching for one of ordinary skill in the art to make or use the broad scope of the invention absent undue experimentation. The specification provides no teaching that other antibodies raised against any other regions except the amino-terminal region would provide the inhibition of ligand to the receptor. The antibodies might not be capable of inhibiting and would actually induce signaling activity which would induce not only CCR2 activity but also other chemokines. Yet still, the antibodies might simply induce cytosolic calcium which would trigger other related cytokine signaling. Absent teaching one of ordinary skill in the art would be required to conduct large quantity of non-routine experimentation to enable the full scope of the claims. Applicants have general statements regarding the antibodies directed to all regions of CCR2. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of antibodies against all regions of CCR2. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant can not rely on the knowledge of those skilled in the art to enable the claims without providing

adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 37-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed antibodies that bind to the amino-terminal domain of the CC-chemokine receptor 2 (CCR2) only. No other antibodies to other regions were disclosed. The specification does not set forth the metes and bounds of all other antibodies directed for all regions of CCR2, there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the structure of antibodies to all the other undisclosed regions. Therefore, a written description of the other claimed antibodies should be disclosed to overcome this rejection. See also *University of*

California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8, 37-42 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-4 of prior U.S. Patent No. 6,406,694 B1. This is a double patenting rejection. The claimed invention is directed to a product, and the already patented claims are also directed to the same product. Applicants have already received patent protection for the product now claimed.

Claims 1, 9-10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 13, 14 of prior U.S. Patent No. 6,451,522 B1. This is a double patenting rejection. The claimed invention is directed to a product, and applicant(s) have already received patent protection for the product.

Claims 1-8, 37-43 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2, 4-6, 11-13, 15, 30-38 of prior U.S. Patent No. 6,312,689 B1. This is a double patenting rejection. The claimed invention is directed to a product, and applicant(s) have already received patent protection for the same product.

Claims of this application conflict with claims of Application No. 09/840,459. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1, 9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 6 of copending Application No. 09/840,459. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-10, 37-43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lind et al (US Patent No. 6,084,075).

The above cited patent meets the broad limitations of the claims (see the claims). The claims are directed to a product. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited patent anticipates the claimed invention. Applicants are reminded that the intended use of a product or its binding capability does not carry patentable weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10, 37-43 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Frade et al (J. Clin. Invest. 1997).

The above cited article disclosed an antibody raised against CCR2 (see page 498, left column, last paragraph, and right column, last full paragraph). Applicants are reminded that antibodies exhibit wide range of binding capability. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to

perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited patent anticipates the claimed invention.

Claims 1-10, 37-43 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Frade et al (J. Immunology, 1997).

The above cited article disclosed an antibody raised against CCR2 (see page 5577, left column, last paragraph). Applicants are reminded that antibodies exhibit wide range of binding capability. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited patent anticipates the claimed invention.

Claims 1-10, 37-43 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lind et al (WO 97/31949, 9/4/1997).

The above cited patent meets the broad limitations of the claims (see the claims). The claims are directed to a product. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Hence, the disclosure of the above cited patent anticipates the claimed invention. Applicants are reminded that the intended use of a product does not carry patentable weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Casselman et al (JOURNAL OF LABORATORY AND CLINICAL MEDICINE, 1995 Nov) 126 (5) 495-502).

The above cited art taught an antibody against MCP-1 which showed that the antibody was capable of neutralizing the MCP-1 activity (see Figure 3, and page 500, right column, middle of third paragraph). In addition, they indicated that the MCP-1 antibody was available to the public (see page 498, left column, first paragraph). The product disclosed in the above cited art is the same as product now being claimed. Applicants are reminded that the intended use of a product or its binding capability does not carry

patentable weight. The cited product would inherently be able to have the same binding capability.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

11/6/2002

ALI R. SALIMI
PRIMARY EXAMINER